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In The

Supreme Court of the United States

October Term, 1994

NOVOPHARM, INC., and NOVOPHARM LTD.,

Petitioners,

v.

BURROUGHS WELLCOME CO.,

Respondent.

Petition For A Writ Of Certiorari To The United States Court Of Appeals For The Federal Circuit

PETITION FOR A WRIT OF CERTIORARI

ROBERT F. GREEN
Counsel of Record
BRUCE M. GAGALA
JEFFREY S. WARD
LEYDIG, VOIT & MAYER, LTD.
Two Prudential Plaza
Suite 4900
Chicago, Illinois 60601
(312) 616-5600

Counsel for Petitioners

COCKLE LAW BRIEF PRINTING CO., (800) 225-6964
OR CALL COLLECT (402) 342-2831

78 pp

QUESTIONS PRESENTED

Whether the Court of Appeals for the Federal Circuit, in affirming a judgment entered under Rule 50(a), *Fed.R.Civ.P.*, improperly usurped the role of the jury by accepting evidence that was presented to the jury by one party, while ignoring evidence to the contrary that was presented in an offer of proof by the other party.

Whether one who exercises skill beyond that of a "pair of hands" to reduce to practice an invention, when others of ordinary skill in the art have failed, is an inventor.

PARTIES TO PROCEEDING

In addition to the parties identified in the caption to the case, Barr Laboratories, Inc. was a party to the proceeding below and Wellcome, Plc. is the parent corporation of the party Burroughs Wellcome Co.

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PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

Petitioners Novopharm Ltd. and Novopharm, Inc. (hereinafter "Novopharm") respectfully petition for a writ of certiorari to review the decision of the United States Court of Appeals for the Federal Circuit, entered in the above-entitled proceedings on November 22, 1994.

OPINION BELOW

The opinion of the Court of Appeals for the Federal Circuit is reported at 40 F.3d 1223 and reproduced in the Appendix ("App.") at pp. 1a-28a. The opinion and order of the district court, entered July 22, 1993, is reported at 828 F.Supp. 1208 and reproduced in the App. at pp. 29a-44a.

JURISDICTION

The judgment of the Court of Appeals for the Federal Circuit was entered on November 22, 1994. Novopharm filed a petition for rehearing, which was denied on December 15, 1994. App. at p. 45a. This Court has jurisdiction to review the judgment of the Court of Appeals pursuant to 28 U.S.C. § 1254(1).

STATUTORY PROVISIONS AND RULES INVOLVED

35 U.S.C. § 116 provides in pertinent part:

> When an invention is made by two or more persons jointly, they shall apply for patent jointly and each make the required oath, except as otherwise provided in this title. Inventors may apply for a patent jointly even though (1) they did not physically work together or at the same time, (2) each did not make the same type or amount of contribution, or (3) each did not make a contribution to the subject matter of every claim of the patent.

Rule 50(a) of the Federal Rules of Civil Procedure provides in pertinent part:

> If during a trial by jury a party has been fully heard on an issue and there is no legally sufficient evidentiary basis for a reasonable jury to find for that party on that issue, the court may determine the issue against that party and may grant a motion for judgment as a matter of law against that party with respect to a claim or defense that cannot under the controlling law be maintained or defeated without a favorable finding on that issue.

STATEMENT OF THE CASE

This case is one of alleged patent infringement which was being tried before a jury. Jurisdiction arose under 28 U.S.C. § 1338(a). Burroughs Wellcome Co. ("BW") charged Novopharm with patent infringement under 35 U.S.C. § 271(e) based on Novopharm Ltd.'s filing of an Abbreviated New Drug Application ("ANDA") with the

Food and Drug Administration for the manufacture and sale of zidovudine ("AZT") capsules. BW charged Novopharm with infringement of U.S. Patent Nos. 4,724,232; 4,828,838; 4,833,130; 4,837,208; 4,818,538; and 4,818,750. These six patents relate to the use of AZT as an effective treatment against HIV/AIDS in humans, and to certain physiological effects of such use.

Novopharm's central defense at trial was that the patents are invalid under 35 U.S.C. § 116 because of a non-joinder of inventors in that BW, with deceptive intent, had failed to join researchers at the National Institutes of Health ("NIH") – Dr. Samuel Broder, Dr. Hiroaki Mitsuya, and Dr. Robert Yarchoan – as coinventors. Novopharm further contended that all the patents in suit are unenforceable because of BW's inequitable conduct in purposefully not joining any of the NIH researchers as coinventors of the patents.

Trial began on June 28, 1993, with the presentation of evidence by BW. The issue of admissibility of certain evidence *vis-a-vis* the district court's legal definition of inventorship was repeatedly raised by all sides. On the morning of July 20, 1993, during the cross-examination by Barr's counsel of the fifth of BW's nearly ninety identified witnesses, the Court's sustained objection as to the admissibility of one of Barr's exhibits started an avalanche which resulted in the entry of judgment against Novopharm pursuant to Rule 50.

At that point, the trial was abruptly recessed. Within hours the district court delivered a "draft" Order to counsel which reflected certain "findings" of fact and the identification of Rule 50, *Fed.R.Civ.P.*, as the procedural

vehicle the court had chosen to end the case. Following a brief discussion shortly thereafter, the district court gave Novopharm until 9:00 a.m. the next morning to consider the draft Order and to prepare an offer of proof.

When the court reconvened the following morning, Novopharm submitted an offer of proof pursuant to Rule 103, *Fed.R.Evid.* Counsel for Novopharm also objected to the Rule 50 procedure and stated that, in contradiction of the draft Order, there remained triable issues, stating, "That's why we have a jury trial." Upon inquiry, counsel for Novopharm asserted that Novopharm had not been fully heard. In the face of that objection, the district court directed that Novopharm could have until 8:30 a.m. the next morning " . . . to be fully heard."

The next morning, Novopharm filed a motion requesting a concrete identification of the issue about which Novopharm was being required to present an offer of proof in order to be fully heard. Ignoring Novopharm's request, the district court refused to further identify the issue and expressly "found" that Novopharm had been fully heard. Judgment under Rule 50(a) was then entered against Novopharm.

Thus, after three and one-half weeks of trial, in which only BW presented evidence to the jury, the district court removed all issues in the case from the jury and entered judgment against Novopharm pursuant to *Fed.R.Civ.P.* 50(a). Novopharm never had the opportunity to present its case to the jury.

The judgment was based upon the district court's legal interpretation of the definition of "conception," an

element of inventorship. The district court stated the law of conception as it believed it to apply to the case:

> The law of conception as understood by the court is comprised of two elements. The first element relates to the state of mind of the inventor – whether he had a definite and permanent idea of the complete and operative invention. This element is subjective; so long as the idea is sufficiently defined and preserved, the law does not require that the inventor's idea be reasonable, scientifically accurate, or capable of being proved. This legal definition of the first element of conception is the object of the parties' current dispute and permeates the whole of the defendants' case.

App. at 36a.

The district court also articulated the role of the NIH scientists as a mere "pair of hands":

> The court notes further that a party who conducts tests wholly at the direction and instruction of another is merely a technician and not a conceiver and acts merely as a "pair of hands." The court finds that this last statement accurately characterizes the role played by Dr. Broder and Dr. Mitsuya. The evidence in the record shows that BW Co. sent Compound S to the NIH with specific instructions and directed the testing performed by Dr. Broder and Dr. Mitsuya.

App at 39a.

The Court of Appeals for the Federal Circuit rejected the district court's interpretation of the law of conception. The Federal Circuit recognized that scientific accuracy and reasonableness, and the ability of the idea to be proved, bear on conception, stating:

> A conception is not complete if the subsequent course of experimentation, especially experimental failures, reveals uncertainty that so undermines the specificity of the inventor's idea that it is not yet a definite and permanent reflection of the complete invention as it will be used in practice.

App. at 14a.

The Court of Appeals for the Federal Circuit proceeded to give credence to the evidence presented by BW to the jury, while ignoring the evidence presented by Novopharm in its offer of proof. The Appeals Court improperly affirmed the district court on five of the six patents in suit. The linchpin of the Federal Circuit's holding is a draft British patent application, prepared by BW before the critical NIH work:

> The '232, '838, '130, '208, and '538 patents encompass compositions and methods of using AZT to treat AIDS. The Burroughs Wellcome inventors claim conception of these inventions prior to the NIH experiments, based on the draft British patent application. That document is not itself a conception, for conception occurs in the inventors' minds, not on paper. The draft simply corroborates the claim that they had formulated a definite and permanent idea of the inventions by the time it was prepared.

App. at 16a.

REASONS FOR GRANTING THE PETITION

SUMMARY OF ARGUMENT

This case is unique. The party with the burden of proof on the only issue to be tried, here Novopharm, was forced to be "fully heard" by the submission of an offer of proof to the trial court. Novopharm never had the opportunity to present evidence to the jury. On appeal, Novopharm's evidence presented in its offer of proof should have been treated equally with the evidence presented to the jury. This did not happen. The Federal Circuit, after enunciating the controlling law, wholly ignored facts in Novopharm's offer of proof which bore directly on the issue of conception: experimental failures of others to show the activity of AZT against HIV, prior to the NIH's success, and the effect of those failures on the BW scientists' states of mind.

The Federal Circuit, by ignoring Novopharm's contrary evidence presented in the only manner allowed by the trial court – via an offer of proof – improperly usurped the role of the jury. The Federal Circuit failed to follow the guidelines of *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 106 S.Ct. 2505 (1986). *Anderson* requires not only that Novopharm's evidence be considered in the light most favorable to Novopharm but also that credibility determinations be made by the trier of fact. Instead, the Federal Circuit overstepped the proper role of an appellate court. Moreover, the Federal Circuit failed to apply its own case precedent holding that one who acts as more than a pair of hands should be accorded inventor status.

Through these errors, the Federal Circuit has so far departed from the accepted and usual course of judicial

proceedings that an exercise of this Court's supervisory power is necessary.

ARGUMENT

The district court's judgment under Rule 50(a) could have been affirmed only if, after examining the record in the light most favorable to Novopharm, and drawing all inferences in Novopharm's favor, the Federal Circuit concluded that the judgment entered was the only one possible under controlling law. In *Anderson*, 477 U.S. at 255, 106 S.Ct. 2513, this Court held that "[c]redibility determinations, the weighing of the evidence, and the drawing of legitimate inferences from the facts are jury functions, not those of the judge, whether he is ruling on a motion for summary judgment or for a directed verdict. The evidence of the non-movant is to be believed, and all justifiable inferences are to be drawn in his favor."

Under the standard for conception enunciated by the Federal Circuit in this case, Novopharm respectfully submits that there is sufficient evidence in the record to make the Federal Circuit's affirmance of the district court's judgment under Rule 50(a) wrong as a matter of law. Specifically, Novopharm presented evidence in its offer of proof that conception of the use of AZT to treat HIV was not complete until the NIH discovered that AZT was effective against HIV. This evidence consists of the utter failure of AZT to show any activity against HIV in experiments conducted by scientists at Duke University and at the FDA against the actual HIV. Those failures undermine any "conception" that may have existed prior to that

work, and destroy the corroborative value of BW's draft patent application.

A more detailed description of this evidence, which was included in Novopharm's offer of proof, and is included in the Appendix at 46a-52a, is set forth below.

I. Work Conducted at Duke and the FDA Showed that AZT Had No Activity Against HIV

In late November, 1984, after BW's St. Clair had reported positive results for AZT only in BW's mouse test, which used a mouse virus, not HIV, BW sent AZT to Dr. Quinnan, the Division Director of the Division of Virology in the Center for Biologies Evaluation at the FDA, to determine if AZT was actually active against HIV. Over the next three months, Quinnan reported several times to BW's Dr. Lehrman regarding the FDA's results. Each time, Quinnan reported that the FDA's results were equivocal, because insufficient data was generated for anyone to know whether AZT was reducing viral replication because it was toxic, or because it was acting as a "true antiviral." Thus, Quinnan's results revealed uncertainty in the BW scientists' idea that AZT would be effective against HIV.

The results BW received from Duke University were worse. On December 4, 1984, Dr. Lehrman forwarded a sample of AZT for testing against HIV to Dr. Weinhold at Duke. He immediately ran two assays, in which, as he reported to BW, AZT showed no activity. In fact, the results indicated that AZT was *toxic*. BW's St. Clair reported these results to her colleagues on February 1, 1985, a mere four days before the draft patent application

was completed. Weinhold next tested AZT on human cells that were newly infected with HIV. The early results, which again showed no activity, were reported to BW. It was not until approximately one month *after* Broder and Mitsuya of the NIH showed BW that AZT was active against HIV in human cells, that Weinhold first reported to BW that AZT had activity against HIV.

This evidence from Novopharm's offer of proof shows that prior to the work of the NIH, the idea that AZT would be effective against HIV was by no means definite and permanent. Just as in *Alpert v. Slatin*, 305 F.2d 891, 894 (C.C.P.A. 1962), where conception was not established until a reduction to practice occurred, the results BW received from its testers did not follow as BW speculated. Applying the standard for conception as enunciated by the Court of Appeals for the Federal Circuit, there is sufficient evidence upon which a jury could find that these experimental failures reveal uncertainty that so undermines the specificity of the BW scientists' idea that their idea cannot be definite and permanent prior to the NIH work. A jury could properly proceed to find a verdict for Novopharm, the party which had the burden of proof. It therefore was improper for the Court of Appeals for the Federal Circuit to affirm the lower court's judgment under Rule 50(a). *Anderson*, 477 U.S. at 255, 106 S.Ct. at 2513.

II. BW's Lack of a Definite and Permanent Idea is Evidenced By Its Actions

That BW's idea of using AZT to treat HIV was in flux, and not "definite and permanent," prior to the NIH's

work, is further evidenced by the stalled nature of BW's AZT project. Although BW's lawyers were working on a draft patent application, BW's scientists were waiting – waiting for some indication that AZT had activity against HIV. Only when that activity was reported to BW by the NIH's Broder did BW's effort to bring AZT to clinical trials begin. A more detailed description of this evidence, which was included in Novopharm's offer of proof, and is included here in the Appendix at 53a-58a, is set forth below.

Prior to receiving the positive results from the NIH, BW's AZT program was going nowhere fast. Clinical trials were on hold, awaiting the results from the NIH. BW had not yet formed a Project Group for AZT, or even proposed that one be formed. However, once Dr. Broder advised BW that AZT had shown activity against HIV, the attitude at BW changed. As BW's St. Clair stated, "[t]hings started happening so fast, that I kind of almost got lost behind". Clinical trials were started. A Project Group was formed.

Thus, work at BW on AZT went from almost none, prior to the NIH results, to a state of "full speed ahead", after those results were made known to BW. This is acknowledged by BW's Dr. Rideout, who stated:

> *Since the activity of AZT was reported to us by the NIH*, my group in the Organic Chemistry Department has worked full time on the synthesis of analogous and prodrugs of AZT to develop a patent position and to search for successors to AZT.

(emphasis added).

III. The Use of Rule 50(a) Was Error

Looking at the totality of the evidence, and using the standard of conception enunciated by the Court of Appeals for the Federal Circuit here, Novopharm respectfully submits that the district court's ruling under Rule 50(a) was wrong, as was the Federal Circuit's affirmation of that ruling. As Novopharm asserted in its offer of proof, prior to the work of the NIH showing that AZT was effective against HIV in human cells, BW had the following information:

(1) Activity of AZT only in mouse tests, which even BW admits is not predictive;

(2) Equivocal, unreliable results from the FDA that did not show AZT's activity against HIV; and

(3) Reports from Duke University that AZT showed no activity against HIV in two separate assays, and in tests using human cells, and that AZT may, in fact, be toxic to human cells.

Thus, Novopharm submits there is sufficient factual evidence upon which a jury could find that, prior to the NIH work, the idea that AZT would be effective against HIV was merely that – an idea, nothing definite, nothing permanent. It was a hope that so far had been crushed by the reality of the FDA and Duke work. There was true experimental uncertainty from the FDA and Duke work. This experimental uncertainty, i.e., whether AZT was in fact active against HIV, given the negative experimental results from Duke and the FDA, precludes a finding under Rule 50(a) that the BW scientists had a complete

conception prior to the work of the NIH and raises a factual inquiry for the jury.

IV. Because the NIH Scientists Were More Than a "Pair of Hands," They Should Have Been Afforded Coinventorship Status

In its Rule 50(a) judgment against Novopharm, the district court also found that NIH scientists, Dr. Broder and Dr. Mitsuya, were not entitled to joint inventor status because they acted as a mere "pair of hands," under the control of BW. The Federal Circuit, however, disagreed. It held that Drs. Broder and Mitsuya were much more than a mere "pair of hands." The court stated:

> That is not to say, however, that the NIH scientists merely acted as a "pair of hands" for the Burroughs Wellcome inventors. Broder and Mitsuya exercised considerable skill in conducting the tests, using their patented cell line to model the responses of human cells infected with HIV. Lehrman did suggest initial concentrations to Broder, but she hardly controlled the conduct of the testing, which necessarily involved interpretation of results for which Broder and Mitsuya, and very few others, were uniquely qualified.

App. at 18a.

Once the Federal Circuit held that the NIH scientists were more than a "pair of hands," it should have conferred joint inventorship status to Drs. Broder and Mitsuya for contributing to the conception of the invention. Under its own precedent, conception is only complete when one of ordinary skill in the art can reduce the

invention to practice without extensive research or experimentation. *Sewall v. Walters*, 21 F.3d 411, 415 (Fed.Cir. 1994).

The Federal Circuit however, failed to do so. This is the first time that a contributor to an invention who has been found to be more than a mere pair of hands in reducing an invention to practice has not been afforded appropriate status as a coinventor.

The reason why there has been no such case is apparent. It simply is not possible to be more than a pair of hands, i.e. to exercise inventive skill, without also being a joint inventor. *Sewall*, 21 F.3d at 415; *Land v. Dreyer*, 155 F.2d 383, 387 (C.C.P.A. 1946).

CONCLUSION

For all of the foregoing reasons, Novopharm respectfully requests that the Court issue a writ of certiorari to review the judgment of the Court of Appeals for the Federal Circuit.

Respectfully submitted,

ROBERT F. GREEN
Counsel of Record
BRUCE M. GAGALA
JEFFREY S. WARD
LEYDIG, VOIT & MAYER, LTD.
Two Prudential Plaza, Suite 4900
Chicago, Illinois 60601
(312) 616-5600

Counsel for Petitioners

United States Court of Appeals
for the Federal Circuit

93-1503, -1504, -1505

BURROUGHS WELLCOME CO.,

Plaintiff-Appellee,

v.

BARR LABORATORIES, INC.,

Defendant-Appellant,

and

NOVOPHARM, INC. and NOVOPHARM, LTD.,

Defendants-Appellants.

E. Anthony Figg, Rothwell, Figg, Ernst & Kurz, of Washington D.C., argued for plaintiff-appellee. With him on the brief were *Steven Lieberman* and *Joseph A. Hynds.* Of counsel was *Mark A. Ash.* Also on the brief were *Thomas F. Curnin, Laura Mezey, Daniel L. Cantor* and *Michael B. Weiss,* Cahill, Gordon & Reindel, of New York, New York. Of counsel were *Paul A. Holcombe, Jr.* and *Susan S. Dunn,* Burrhoughs Wellcome Co., Research Triangle Park, North Carolina.

Dan K. Webb, Winston & Strawn, of Chicago, Illinois, argued for defendant-appellant. With him on the brief were *Eric L. Hirschhorn, George C. Lombardi, James F. Hurst* and *Monique M. Vasilchik.* Also on the brief were *Myron Cohen* and *Michael C. Stuart,* Cohen, Pontani, Lieberman & Pavane, of New York, New York. *Robert F. Green,* Leydig, Voit & Mayer, LTD., of Chicago, Illinois, argued for defendants-appellants. With him on the brief were

Bruce M. Gagala, Richard M. Johnson and *Regina M. Anderson.* Of counsel was *Jeffrey S. Ward,* Chicago, Illinois.

Appealed from: U.S. District Court for the
Eastern District of North Carolina

Judge Howard

United States Court of Appeals
for the Federal Circuit

93-1503, -1504, -1505

BURROUGHS WELLCOME CO.,

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Defendant-Appellant,

and

NOVOPHARM, INC. and NOVOPHARM, LTD.,

Defendants-Appellants.

DECIDED: November 22, 1994

Before MAYER, LOURIE, and SCHALL, *Circuit Judges.*

MAYER, *Circuit Judge.*

Barr Laboratories, Inc., Novopharm, Inc., and Novopharm, Ltd., appeal the order of the United States District Court for the Eastern District of North Carolina, *Burroughs Wellcome Co. v. Barr Lab., Inc.,* 828 F. Supp. 1208

(E.D.N.C. 1993), granting the motion of Burroughs Wellcome Co. for judgment as a matter of law that six United States patents were not invalid and were infringed. We affirm in part, vacate in part, and remand.

Background

Burroughs Wellcome Co. is the owner of six United States patents that cover various preparations of 3'-azidothymidine (AZT) and methods for using that drug in the treatment of persons infected with the human immunodeficiency virus (HIV).[1] Each of these patents names the same five inventors – Janet Rideout, David Barry, Sandra Lehrman, Martha St. Clair, and Phillip Furman (Burroughs Wellcome inventors) – all of whom were employed by Burroughs Wellcome at the time the inventions were alleged to have been conceived. The defendants-appellants concede that all five are properly named as inventors on the patents.

Burroughs Wellcome's patents arise from the same parent application filed on September 17, 1985.[2] Five of

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[1] Although two of the patents claim pharmaceutical compositions of AZT, not methods of treatment per se, the parties treat all of the patents as covering the particular use of AZT as a treatment for AIDS and its symptoms. The district court adopted this interpretation and applied the patents as though all claimed methods of treatment; no party argues for another interpretation, so we do the same.

[2] The following patents are at issue: U.S. Patent No. 4,724,232 (the '232 patent), filed September 17, 1985, issued February 9, 1988; No. 4,828,838 (the '838 patent), filed October 21, 1987, issued May 9, 1989; No. 4,833,130 (the '130 patent), filed October 20, 1987, issued May 23, 1989; No. 4,837,208 (the

the patents relate to the use of AZT to treat patients infected with HIV or who have acquired immunodeficiency syndrome (AIDS).[3] The other patent, the '750 patent, covers a method of using AZT to increase the T-lymphocyte count of persons infected with HIV.[4]

'208 patent), filed October 20, 1987, issued June 6, 1989; No. 4,818,538 (the '538 patent), filed October 21, 1987, issued April 4, 1989; and No. 4,818,750 (the '750 patent), filed October 20, 1987, issued April 4, 1989.

[3] Claim 1 of the '232 patent covers "[a] method of treating a human having acquired immunodeficiency syndrome comprising the oral administration of an effective acquired immunodeficiency syndrome treatment amount of 3'-azido-3'-deoxythymidine to said human."

Claim 1 of the '838 patent covers "[a] pharmaceutical preparation comprising a capsule containing 5 to 500 mg of 3'-azido-3'-deoxythymidine."

Claim 1 of the '130 patent covers "[a] method of treating a human having an HTLV III virus infection comprising administering to said human an effective HTLV III virus treatment amount of 3'-azido-3'-deoxythymidine."

Claim 1 of the '208 patent covers "[a] method of treating a human having antibodies to the HTLV III virus which comprises administering to said human an effective HTLV III treatment amount of 3'-azido-3'-deoxythymidine."

Claim 1 of the '538 patent covers "[a] sealed container including a pharmaceutical composition in unit dosage form comprising 5 to 500 mg of 3'-azido-3'-deoxythymidine together with a pharmaceutically acceptable solid carrier."

[4] Claim 1 of the '750 patent covers "[a] method of increasing the number of T-lymphocytes in a human infected with the HTLV III virus comprising administering to said human an effective amount of 3'-azido-3'-deoxythymidine or a pharmaceutically acceptable alkali metal, alkaline earth or ammonium salt thereof."

In the early 1980s, scientists began to see patients with symptoms of an unknown disease of the immune system, now known as AIDS. The disease attacks and destroys certain white blood cells known as CD4 T-lymphocytes or T-cells, which form an important component of the body's immune system. The level of destruction eventually becomes so great that the immune system is no longer able to mount an effective response to infections that pose little threat to a healthy person.

In mid-1984, scientists discovered that AIDS was caused by a retrovirus, known as HTLV III or, more commonly today, HIV. After the identification of HIV, Burroughs Wellcome began to search for a cure, screening compounds for antiretroviral activity using two murine (or mouse) retroviruses, the Friend leukemia virus and the Harvey sarcoma virus.

At about this time, scientists at the National Institutes of Health (NIH), led by Samuel Broder, were looking for effective AIDS therapies as well. Unlike Burroughs Wellcome, Broder and his colleagues used live HIV, and were able to develop a test that could demonstrate a compound's effectiveness against HIV in humans using a unique line of T-cell clones (the ATH8 cell line). The NIH scientists began to seek compounds from private pharmaceutical companies for screening in their cell line. After Burroughs Wellcome contacted Broder in the fall of 1984, he agreed to accept compounds from Burroughs Wellcome under code for testing against live HIV.

Burroughs Wellcome's Rideout selected AZT and a number of other compounds for testing in the murine screens on October 29, 1984. The tests, performed at

Burroughs Wellcome facilities by St. Clair, showed that AZT had significant activity against both murine retroviruses at low concentrations. In light of these positive results, the Burroughs Wellcome inventors met on December 5, 1984, to discuss patenting the use of AZT in the treatment of AIDS. Burroughs Wellcome's patent committee thereafter recommended that the company prepare a patent application for future filing. By February 6, 1985, the company had prepared a draft application filing in the United Kingdom. The draft disclosed using AZT to treat patients infected with HIV, and set out various pharmaceutical formulations of the compound in an effective dosage range to treat HIV infection.

Two days earlier, on February 4, 1985, Burroughs Wellcome had sent a sample of AZT, identified only as Compound S, to Broder at NIH. In an accompanying letter, Lehrman told Broder of the results of the murine retrovirus tests and asked that he screen the compound for activity against HIV in the ATH8 cell line. Another NIH scientist, Hiroaka Mitsuya, performed the test in mid-February 1985, and found that Compound S was active against HIV. Broder informed Lehrman of the results by telephone on February 20, 1985. Burroughs Wellcome filed its patent application in the United Kingdom on March 16, 1985.

After Burroughs Wellcome learned that AZT was active against HIV, it began the process of obtaining Food and Drug Administration (FDA) approval for AZT as an AIDS therapy. As a part of the clinical trials leading to FDA approval, Broder and another NIH scientist, Robert Yarchoan, conducted a Phase I human patient study which showed that treatment with AZT could result in an

increase in the patient's T-cell count. Broder reported this result to Lehrman on July 23, 1985. In 1987, the FDA approved AZT for marketing by Burroughs Wellcome; Burroughs Wellcome markets the drug for treatment of HIV infection under the trademark Retrovir.

On March 19, 1991, Barr Laboratories, Inc. (Barr) sought FDA approval to manufacture and market a generic version of AZT by filing an Abbreviated New Drug Application (ANDA) pursuant to 21 U.S.C. § 355(j) (1988). As part of the process, Barr certified to the FDA that Burroughs Wellcome's patents were invalid or were not infringed by the product described in its ANDA. After Barr informed Burroughs Wellcome of its action, Burroughs Wellcome commenced this case for patent infringement against Barr on May 14, 1991, alleging technical infringement of its patents under 35 U.S.C. § 271(e)(2)(A) (1988).

Barr filed a counterclaim under 35 U.S.C. § 256 (1988) seeking correction of the patents to list Broder and Mitsuya as coinventors. Barr admitted that its AZT product would infringe the patents, but contended that it did not because Barr had obtained a license to manufacture and sell AZT from the government, which should be deemed the owner of the interest of coinventors Broder and Mitsuya in the AZT patents. Burroughs Wellcome denied that Broder and Mitsuya were coinventors and also responded that the assertion of any rights of Broder, Mitsuya, or the government in the patents was barred by laches, estoppel, and waiver.

Thereafter, Novopharm, Ltd. filed an ANDA of its own, seeking approval to manufacture and market its

generic version of AZT. Burroughs Wellcome filed infringement suits against Novopharm, Ltd. and its American subsidiary Novopharm, Inc., which were consolidated with the suit against Barr.[5] Like Barr, Novopharm, Ltd. admitted that its AZT product would infringe the claims of the six patents, but for the failure of Burroughs Wellcome to name the NIH scientists as coinventors of the subject matter of the patents. Although Novopharm, Inc. agreed to be bound by any injunction issued against its parent, it argued that it had not infringed the patents because it had not filed an ANDA and had no AZT product of its own.[6] Novopharm contended that Broder and Mitsuya should have been named as inventors on five of the patents, and contended that Broder and Yarchoan were coinventors of the '750 patent. It maintained that the patents were invalid because of the alleged nonjoinder, and because Burroughs Wellcome had omitted the coinventors with deceptive intent, the patents were unenforceable for inequitable conduct.

After more than three weeks of trial while Burroughs Wellcome was still in the process of presenting its case,

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[5] Novopharm, Inc. and Novopharm, Ltd. are jointly represented by counsel and make many of the same arguments on appeal. Except where it is more appropriate to refer to them individually, we will refer to them together as Novopharm.

[6] Burroughs Wellcome alleges that Novopharm, Inc. is liable for the infringement by Novopharm, Ltd. on grounds that it participated in or induced Novopharm, Ltd.'s infringing activities. But Burroughs Wellcome had the burden of proving infringement by Novopharm, Inc. and on the record before us there is simply no evidence to support a conclusion on this factual question. The judgment against Novopharm, Inc. is vacated.

the district court granted Burroughs Wellcome's motion for judgment as a matter of law against all of the defendants, concluding that the Burroughs Wellcome inventors had conceived of the subject matter of the inventions at some time before February 6, 1985, without the assistance of Broder, Mitsuya, or Yarchoan. The court rejected the arguments of Barr and Novopharm that they should be allowed to present evidence that the Burroughs Wellcome inventors had no reasonable belief that the inventions would actually work – that AZT was in fact active against HIV – until they were told the results of the NIH testing.

The court also rejected Novopharm's argument that the Burroughs Wellcome inventors had not conceived the invention of the '750 patent – the use of AZT to increase a patient's T-cell count – before July 23, 1985, when Broder reported the results of the NIH patient study to Lehrman. The court concluded that the increase in T-cell count was an obvious phenomenon known to the inventors that would result from administration of AZT. And the district court denied Barr's renewed motion for partial summary judgment on Burroughs Wellcome's equitable defenses to its counterclaim for correction of the patents under section 256.

Discussion

The arguments of both Barr and Novopharm are directed to when the inventors conceived the invention. Burroughs Wellcome says it was before they learned the results of the NIH tests; Barr and Novopharm say that confirmation of the inventions' operability, which came from the NIH tests, was an essential part of the inventive

process. If Burroughs Wellcome is right, then the patents name the proper inventors, they are not invalid, and the appellants are liable for infringement. If Barr and Novopharm are correct, then Broder, Mitsuya, and Yarchoan should have been named as joint inventors and the resolution of Burroughs Wellcome's infringement suits is premature.

The district court's grant of judgment as a matter of law under Rule 50(a) is subject to de novo review. *Read Corp. v. Portec, Inc.*, 970 F.2d 816, 821, 23 USPQ2d 1426, 1431 (Fed. Cir. 1992). We must apply the same standard as did that court, examining the record in the light most favorable to the nonmovant and drawing inferences in that party's favor. We may affirm only if the judgment entered was the only one possible under the controlling law. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 250 (1986).

A joint invention is the product of a collaboration between two or more persons working together to solve the problem addressed. 35 U.S.C. § 116 (1988); *Kimberly-Clark Corp. v. Procter & Gamble Distrib. Co.*, 973 F.2d 911, 917, 23 USPQ2d 1921, 1926 (Fed. Cir. 1992). People may be joint inventors even though they do not physically work on the invention together or at the same time, and even though each does not make the same type or amount of contribution. 35 U.S.C. § 116. The statute does not set forth the minimum quality or quantity of contribution required for joint inventorship.

Conception is the touchstone of inventorship, the completion of the mental part of invention. *Sewall v. Walters*, 21 F.3d 411, 415, 30 USPQ2d 1356, 1359 (Fed. Cir.

1994). It is "the formation in the mind of the inventor, of a definite and permanent idea of the complete and operative invention, as it is hereafter to be applied in practice." *Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1376, 231 USPQ 81, 87 (Fed. Cir. 1986) (citation omitted). Conception is complete only when the idea is so clearly defined in the inventor's mind that only ordinary skill would be necessary to reduce the invention to practice, without extensive research or experimentation. *Sewall*, 21 F.3d at 415, 30 USPQ2d at 1359; *see also Coleman v. Dines*, 754 F.2d 353, 359, 224 USPQ 857, 862 (Fed. Cir. 1985) (conception must include every feature of claimed invention). Because it is a mental act, courts require corroborating evidence of a contemporaneous disclosure that would enable one skilled in the art to make the invention. *Coleman v. Dines*, 754 F.2d at 359, 224 USPQ at 862.

Thus, the test for conception is whether the inventor had an idea that was definite and permanent enough that one skilled in the art could understand the invention; the inventor must prove his conception by corroborating evidence, preferably by showing a contemporaneous disclosure. An idea is definite and permanent when the inventor has a specific, settled idea, a particular solution to the problem at hand, not just a general goal or research plan he hopes to pursue. *See Fiers v. Revel*, 984 F.2d 1164, 1169, 25 USPQ2d 1601, 1605 (Fed. Cir. 1993); *Amgen, Inc. v. Chugai Pharmaceutical Co.*, 927 F.2d 1200, 1206, 18 USPQ2d 1016, 1021 (Fed. Cir. 1989) (no conception of chemical compound based solely on its biological activity). The conception analysis necessarily turns on the inventor's ability to describe his invention with particularity. Until he can do so, he cannot prove possession of

the complete mental picture of the invention. These rules ensure that patent rights attach only when an idea is so far developed that the inventor can point to a definite, particular invention.

But an inventor need not know that his invention will work for conception to be complete. *Applegate v. Scherer*, 332 F.2d 571, 573, 141 USPQ 796, 799 (CCPA 1964). He need only show that he had the idea; the discovery that an invention actually works is part of its reduction to practice. *Id.; see also Oka v. Youssefyeh*, 849 F.2d 581, n.1, 7 USPQ2d 1169, 1171 n.1 (Fed. Cir. 1988).

Barr and Novopharm suggest that the inventor's definite and permanent idea must include a reasonable expectation that the invention will work for its intended purpose. They argue that this expectation is of paramount importance when the invention deals with uncertain or experimental disciplines, where the inventor cannot reasonably believe an idea will be operable until some result supports that conclusion. Without some experimental confirmation, they suggest, the inventor has only a hope or an expectation, and has not yet conceived the invention in sufficiently definite and permanent form. But this is not the law. An inventor's belief that his invention will work or his reasons for choosing a particular approach are irrelevant to conception. *MacMillan v. Moffett*, 432 F.2d 1237, 1239, 167 USPQ 550, 552 (CCPA 1970).

To support their reasonable expectation rule, Barr and Novophharm point to a line of cases starting with *Smith v. Bousquet*, 111 F.2d 157, 45 USPQ 347 (CCPA 1940),

establishing the so-called doctrine of simultaneous conception and reduction to practice.[7] *Smith* was an interference priority contest between alleged inventors of the use of two known compounds as insecticides. Both parties asserted priority based on testing of the compounds against selected insect species. Noting the unpredictability of the experimental sciences of chemistry and biology, in particular the uncertain relationship between chemical structure and biological activity, *Smith* declined to find conception until the invention had been reduced to practice by the filing of the first patent application. *Id.* at 162, 45 USPQ at 352. Barr and Novopharm read this and subsequent cases to establish, or at lest support, their rule that conception of an invention in an unpredictable field occurs only when the inventor has reasonable grounds to believe the invention will work.

But these cases do not stand for the proposition that an inventor can never conceive an invention in an unpredictable or experimental field until reduction to practice. In rejecting the asserted evidence of conception, *Smith* said as to one of the compounds:

> it is apparent from the record that neither [party] had in mind at the time the suggestions were originally made, nor at any time thereafter, until successful tests, if any, were made, what insects, if any, it might be effective against, or

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[7] Barr and Novopharm also point to dictum in *Biel v. Chessin*, 347 F.2d 898, 146 USPQ 293 (CCPA 1965), suggesting that conception of a method of treating the human body requires a reasonable understanding that the method will work for its intended purpose. No court has applied this dictum as controlling, and we decline to do so here.

> how it might be applied to produce the desired results. Accordingly, neither party had a definite idea of the "complete and operative invention" here involved prior to a successful reduction – actual or constructive – of it to practice.

Id. Thus, in awarding priority to Smith based on his constructive reduction to practice, the court relied not on the inherent unpredictability of the science, but on the absence of any evidence to corroborate an earlier conception for either of the parties.

It is undoubtedly true that "[i]n some instances, an inventor is unable to establish a conception until he has reduced the invention to practice through a successful experiment." *Amgen*, 927 F.2d at 1206, 18 USPQ2d at 1021; *Alpert v. Slatin*, 305 F.2d 891, 894, 134 USPQ 296, 299 (CCPA 1962) (no conception "where results at each step do not follow as anticipated, but are achieved empirically by what amounts to trial and error"). But in such cases, it is not merely because the field is unpredictable: the alleged conception fails because, as in *Smith*, it is incomplete. Then the event of reduction to practice in effect provides the only evidence to corroborate conception of the invention.

Under these circumstances, the reduction to practice can be the most definitive corroboration of conception, for where the idea is in constant flux, it is not definite and permanent. A conception is not complete if the subsequent course of experimentation, especially experimental failures, reveals uncertainty that so undermines the specificity of the inventor's idea that it is not yet a definite and permanent reflection of the complete invention as it will be used in practice. *See Amgen*, 927 F.2d at 1207, 18

USPQ2d at 1021 (no conception until reduction to practice where others tried and failed to clone gene using suggested strategy); *Rey-Bellet v. Engelhardt*, 493 F.2d 1380, 1387, 181 USPQ 453, 457-58 (CCPA 1974) (focusing on nature of subsequent research as indicator that inventors encountered no perplexing intricate difficulties). It is this factual uncertainty, not the general uncertainty surrounding experimental sciences, that bears on the problem of conception.

Barr and Novopharm argue for a broader reading of *Amgen* and *Fiers* in support of their reasonable expectation rule. Both of these cases involve conception of a DNA encoding a human protein – a chemical compound. Conception of a chemical substance includes knowledge of both the specific chemical structure of the compound and an operative method of making it. *Fiers*, 984 F.2d at 1169, 25 USPQ2d at 1604; *Amgen*, 927 F.2d at 1206, 18 USPQ2d at 1021; *Oka*, 849 F.2d at 583, 7 USPQ2d at 1171. The alleged inventors in *Fiers* and *Amgen* claimed conception of their respective inventions before they knew relevant chemical structure – the nucleotide sequence – so the courts found no conception until experimentation finally revealed that structure. Here, though, Burroughs Wellcome's inventions use a compound of known structure; the method of making the compound is also well known.

We emphasize that we do not hold that a person is precluded from being a joint inventor simply because his contribution to a collaborative effort is experimental. Instead, the qualitative contribution of each collaborator is the key – each inventor must contribute to the joint arrival at a definite and permanent idea of the invention as it will be used in practice.

Nor do we suggest that a bare idea is all that conception requires. The idea must be definite and permanent in the sense that it involves a specific approach to the particular problem at hand. It must also be sufficiently precise that a skilled artisan could carry out the invention without undue experimentation. And, of course, the alleged conception must be supported by corroborating evidence. On the facts before us, it is apparent that the district court correctly ruled against Barr and Novopharm as to five of the patents, but that the court's judgment as to the sixth, the '750 patent, was premature.

The '232, '838, '130, '208, and '538 patents encompass compositions and methods of using AZT to treat AIDS. The Burroughs Wellcome inventors claim conception of these inventions prior to the NIH experiments, based on the draft British patent application. That document is not itself a conception, for conception occurs in the inventors' minds, not on paper. The draft simply corroborates the claim that they had formulated a definite and permanent idea of the inventions by the time it was prepared.

The Burroughs Wellcome inventors set out with the general goal of finding a method to treat AIDS, but by the time Broder confirmed that AZT was active against HIV, they had more than a general hope or expectation. They had thought of the particular antiviral agent with which they intended to address the problem, and had formulated the idea of the inventions to the point that they could express it clearly in the form of a draft patent application, which Barr and Novopharm concede would teach one skilled in the art to practice the inventions. The draft expressly discloses the intended use of AZT to treat AIDS. It sets out the compound's structure, which, along

with at least one method of preparation, was already well known. The draft also discloses in detail both how to prepare a pharmaceutical formulation of AZT and how to use it to treat a patient infected with HIV. The listed dosages, dose forms, and routes of administration conform to those eventually approved by the FDA. The draft shows that the idea was clearly defined in the inventors' minds; all that remained was to reduce it to practice – to confirm is operability and bring it to market. *See Haskell v. Colebourne,* 671 F.2d 1362, 1365-66, 213 USPQ 192, 194 (CCPA 1982) (enabling draft patent application sufficient to corroborate conception).

An examination of the events that followed the preparation of Burroughs Wellcome's draft confirms the soundness of the conception. Broder and Mitsuya received from Burroughs Wellcome a group of compounds, known to Broder and Mitsuya only by code names, selected for testing by the Burroughs Wellcome inventors. They then tested those compounds for activity against HIV in their patented cell line. The test results revealed for the first time that one of the compounds, later revealed to be AZT, was exceptionally active against the virus.

Here, though, the testing was brief, simply confirming that operability of what the draft application disclosed. True, the science surrounding HIV and AIDS was unpredictable and highly experimental at the time the Burroughs Wellcome scientists made the inventions. But what matters for conception is whether the inventors had a definite and permanent idea of the operative inventions. In this case, no prolonged period of extensive research, experiment, and modification followed the

alleged conception. By all accounts, what followed was simply the normal course of clinical trials that mark the path of any drug to the marketplace.

That is not to say, however, that the NIH scientists merely acted as a "pair of hands" for the Burroughs Wellcome inventors. Broder and Mitsuya exercised considerable skill in conducting the tests, using their patented cell line to model the responses of human cells infected with HIV. Lehrman did suggest initial concentrations to Broder, but she hardly controlled the conduct of the testing, which necessarily involved interpretation of results for which Broder and Mitsuya, and very few others, were uniquely qualified. But because the testing confirmed the operability of the inventions, it showed that the Burroughs Wellcome inventors had a definite and permanent idea of the inventions. It was part of the reduction to practice and inured to the benefit of Burroughs Wellcome.

Barr and Novopharm allege error in the district court's refusal to hear their evidence of the poor predictive value of the murine retrovirus screens for activity against HIV. Regardless of the predictive value of the murine tests, however, the record shows that soon after those tests, the inventors determined, for whatever reason, to use AZT as a treatment for AIDS, and they prepared a draft patent application that specifically set out the inventions, including an enabling disclosure. Obviously, enablement and conception are distinct issues, and one need not necessarily meet the enablement standard of 35 U.S.C. § 112 to prove conception. *See Fiers*, 984 F.2d at 1169, 25 USPQ2d at 1605. But the enabling disclosure does suffice in this case to confirm that the inventors had

concluded the mental part of the inventive process – that they had arrived at the final, definite idea of their inventions, leaving only the task of reduction to practice to bring the inventions to fruition.

The question is not whether Burroughs Wellcome reasonably believed that the inventions would work for their intended purpose, the focus of the evidence offered by Barr and Novopharm, but whether the inventors had formed the idea of their use for that purpose in sufficiently final form that only the exercise of ordinary skill remained to reduce it to practice. *See MacMillan v. Moffett*, 432 F.2d at 1239, 167 USPQ at 552 (Inventor's "reasons or lack of reasons for including U-5008 are not relevant to the question of conception. The important thing is that he did think in definite terms of the method claimed."). Whether or not Burroughs Wellcome believed the inventions would in fact work based on the mouse screens is irrelevant.

We do not know precisely when the inventors conceived their inventions, but the record shows that they had done so by the time they prepared the draft patent application that thoroughly and particularly set out the inventions as they would later be used. The district court correctly ruled that on this record, the NIH scientists were not joint inventors of these inventions.

The '750 patent is another question. It claims "[a] method of increasing the number of T-lymphocytes in a human infected with the [HIV] virus comprising administering to said human an effective amount of" AZT. Novopharm argues that there is no evidence, under any

test of inventorship, that the Burroughs Wellcome inventors conceived of this invention until after the Phase I patient study conducted by Broder and Yarchoan revealed that AZT could lead to increased levels of T-cells in AIDS patients.

Novopharm is right that the record is devoid of any statement that the inventors thought AZT could raise a patient's T-cell levels, but evidence need not always expressly show possession of the invention to corroborate conception. The district court held that the record supported conception as a matter of law, concluding that "an increase in T-lymphocyte count was an 'obvious,' natural phenomenon known to the [Burroughs Wellcome] inventors that would result from the inhibition of a retrovirus." *Burroughs Wellcome Co. v. Barr Lab., Inc.*, 828 F. Supp. at 1213. Burroughs Wellcome argues that this conclusion was proper because increased T-cell count is simply an obvious property or use of the greater discovery at issue here, the treatment of HIV infection with AZT. Because an increase in T-lymphocytes follows inevitably from treatment of AIDS patients with AZT, Burroughs Wellcome says, Broder and Yarchoan merely observed that the method invented by the Burroughs Wellcome inventors had qualities that the inventors failed to perceive. Burroughs Wellcome says this is not an inventive contribution to the claims of any of the AZT patents.

But even though all six patents arise from the same parent application and are subject to terminal disclaimers to avoid rejection for obviousness-type double patenting,

each patent claims a different invention.[8] *See In re Longi*, 759 F.2d 887, 892, 225 USPQ 645, 648 (Fed. Cir. 1985) (inventor can get only one patent for any single invention). It is true that the Patent Office determined that the method of the '750 patent would have been obvious to those skilled in the art in light of the inventions claimed in the other patents. That is, however, irrelevant to the question whether the Burroughs Wellcome inventors had conceived of the invention before they learned the results of the Phase I trials. For conception, we look not to whether one skilled in the art could have thought of the invention, but whether the alleged inventors actually had in their minds the required definite and permanent idea. *Cf. Bosies v. Benedict*, 27 F.3d 539, 543, 30 USPQ2d 1862, 1865 (Fed. Cir. 1994) (testimony of noninventor as to noninventor's understanding of inventor's written formula insufficient to prove conception). The record does not now support resolution of this question as a matter of law.

The alleged conception is supported by testimony of Burroughs Wellcome's experts, Burroughs Wellcome's

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[8] We must assume for the purposes of this case that the '750 patent is drawn to an invention different from each of the other five patents. The parties do not ask us to decide whether claims drawn to an effect or mechanism of action of AZT – its ability to raise T-cell count – reach the same invention as (that is, are inherent in) claims drawn to use of the drug to treat HIV infection or AIDS, and we express no opinion on that. The dissent therefore goes beyond the issues presented and the record before us to decide on the basis of what the dissenting judge thinks he knows. That is not the role of an appellate court.

draft Phase I protocol, and the same draft patent application that corroborates conception of the other five inventions. The experts testified that those skilled in the art at the time expected increased immune function to accompany inhibition of HIV. The draft patent application discloses that HIV preferentially destroys T-cells, that AIDS is associated with progressive depletion of T-cells, and that AZT is an effective treatment for HIV infection. Finally, the draft protocol directs the administrators of the Phase I study to monitor patients' T-lymphocyte count. This evidence supports an inference that the Burroughs Wellcome inventors did have the necessary definite and permanent idea, for, given the virus' effect on T-lymphocytes, it seems logical to conclude that stopping the virus might reverse the process of T-cell destruction and restore the body's immune system to a pre-infection state. If this were the only evidence in the record, the court's judgment would be sustained.

But Novopharm offered evidence suggesting that one skilled in the art would not have expected T-cell count to rise. On deposition, Broder testified that prior to the first patient study, "no one knew whether there was such a thing as recovery" of T-cells, based on the NIH's experience with suramin, a drug that entered clinical trials before AZT. Although suramin showed some activity against HIV, inhibition of the retrovirus apparently was not accompanied by increases in T-cell count or restoration of immune functions. Of course, there might be any number of other explanations for the results of the suramin trials; but they might suggest that although those skilled in the art recognized the significance of T-lymphocyte levels in HIV infection and AIDS, they might have

expected inhibition of the virus simply to halt the continuing destruction of T-cells, not to increase T-cell count and restore immune function. This could support an inference that the inventors themselves did not conceive the invention prior to the Phase I study.

Novopharm also contends that Burroughs Wellcome prepared its Phase I protocol in collaboration with Broder and the NIH, possibly from a draft protocol prepared by Broder and Yarchoan pursuant to their study of suramin. These contentions are relevant to the conception inquiry for they tend to undermine the corroborative value of the draft protocol, and might even support joint inventorship based on that draft. *See Coleman v. Dines*, 745 F.2d at 360, 224 USPQ at 863 (document's co-author cannot be considered sole inventor of invention disclosed in document without further proof). Because under Rule 50(a) all inferences must be taken against the moving party, the court's ruling on the '750 patent was inappropriate, and we vacate the judgment to that extent and remand for further proceedings.

Conclusion

Accordingly, the judgment of the United States District Court for the Eastern District of North Carolina is affirmed in part, vacated in part, and remanded.

COSTS

All parties will bear their own costs.

AFFIRMED IN PART, VACATED IN PART, AND REMANDED

United States Court of Appeals for the Federal Circuit

93-1503, -1504, -1505

BURROUGHS WELCOME CO.,
Plaintiff-Appellee,

v.

BARR LABORATORIES, INC.,
Defendant-Appellant,

and

NOVOPHARM, INC. and NOVOPHARM, LTD.,
Defendants-Appellants.

LOURIE, *Circuit Judge*, concurring-in-part and dissenting-in-part.

I concur in the majority's decision with respect to the '232, '838, '130, '208, and '538 patents, and join the opinion except for the following:

I do not agree that reduction to practice is corroboration of conception and that the completeness of a conception is affected by subsequent experimental success or failure. These statements confuse the idea of conception with both corroboration and reduction to practice. A conception must be judged as to its completeness in relation to the invention being claimed. It must also be corroborated by evidence independent of the inventor. If subsequent experimentation shows that an invention that was only conceived does not work, that fact does not vitiate the earlier conception. A conception not later reduced to practice may have little significance, but it is important that we not confuse concepts. The conception was still a conception. It is of course possible for an invention to be

reduced to practice constructively, *i.e.*, by filing a patent application, rather than actually, by doing the work, in which case the reduction to practice clearly says nothing about the completeness of the conception. Moreover, what matters, in addition to the completeness of a conception, is its date. Corroboration must be of the date of the conception. If the only "corroboration" of the conception is its reduction to practice, corroboration has not occurred concerning the alleged date of conception. Finally on this point, reduction to practice by the inventor is not corroboration because corroboration must be independent of the inventor. Corroboration is not a demonstration that the conceived invention works; it is evidentiary proof that the mental act of invention occurred on a certain date.

I also believe that the issue of joint inventorship is irrelevant here and therefore confusing. If the Burroughs Wellcome inventors had a complete conception, as we hold, then the NIH scientists were not inventors because the invention had already been made, not because of any shortcomings in their inventive contributions. Thus, there is no need to discuss joint inventorship at all.

I respectfully dissent from the vacating of the court's judgment concerning the '750 patent. I believe that the method of the '750 patent is an inherent, inevitable result of the practice of the other method patents claiming treatment of HIV or AIDS. It seems to be the (or a) mechanism by which the other methods find their use.

Even if it is true that the first verification or articulation of the increase in the T-cell count occurred in the hands of NIH scientists, this finding inures to the benefit

of those who conceived the method of treatment that led to it. The method of the '750 patent is merely a refined definition of the method of the '232 patent, which issued from the original application. The '130 and '208 patents, which also came from applications later filed with the '750 and the composition patents, are also modifications of the original filing. It is common practice for applicants to claim all aspects of their invention and that is what appears to have happened here. An inventor is entitled to the inherent benefits that flow from his or her invention. It is improper to split the inventorship of what is one invention merely because the means by which it was achieved was later verified by scientists acting pursuant to the original conceivers.

The PTO of course issued these patents. During its examination, it determined that the '750 method was obvious over the '232 method. Given a terminal disclaimer, this led to the grant of the patent. More than being obvious, however, the method was inherent in the '232 method and therefore lacking in novelty. *See* 35 U.S.C. §102 (1988). If, as I believe, the '750 invention does lack novelty over the other patents, its validity may be in question on the ground of double patenting because a terminal disclaimer is not effective to cure a double patenting problem when the inventions are the same. As long as the inventive entities are also the same, however, it doesn't really matter.

Even assuming that the '750 method is a separate invention, the majority concedes that evidence supports an inference that the Burroughs Wellcome inventors alone conceived the method. The majority goes off the track, however, in relying on Novopharm's offer of evidence

that one would not have expected the T-cell count to rise. This is irrelevant if Burroughs Wellcome's inventors had the conception, because the opinion earlier correctly holds that a reasonable expectation of success is not necessary to a conception.

The majority here is inviting the trial court on remand and motion, *see* 35 U.S.C. §256 (1988), to partially split the inventorship, and presumably also the ownership, of this related collection of patents claiming the physical act of "treating" and the result which the treatment accomplishes. This makes no sense. It amounts to deciding that treating a person in pain with aspirin is one invention and invoking the pain-relieving mechanism by means of that treatment is another. One cannot apparently treat HIV-infected humans with AZT without also increasing the level of T-lymphocytes. The panel is thus inconsistent in upholding the conclusion of the trial court that Burroughs Wellcome's scientists alone conceived the invention of using AZT to treat HIV infection, but then failing to arrive at the same conclusion regarding a patent claiming one of the sequelae of that use.

The real result of the majority's vacating the court's decision on the '750 patent is that, while it may believe that it is affirming the decision on the other patents, it may in practical effect be destroying Burroughs Wellcome's exclusivity for its invention and creating a whole new set of questions. If the trial court joins the NIH inventors, and NIH has licensed the patent to companies intending to sell AZT, will those companies infringe the '232 and other patents? Is the terminal disclaimer still valid, lacking the consent of one of the assignees? Without a valid terminal disclaimer, is the '750 patent valid?

While these questions are not before us, exploring them illustrates the strange consequences of the majority's decision. On the other hand, if the trial court confirms its finding that the T-lymphocyte "invention" was essentially the same invention and inured to the benefit of Burroughs Wellcome, the remand will have been superfluous. Useless and inefficient litigation and burdening of the courts will have resulted.

The trial court's decision should be affirmed across the board because it correctly found that the Burroughs Wellcome inventors solely conceived and are entitled to the inventive benefit of all the claimed inventions.

THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF NORTH CAROLINA
NEW BERN DIVISION

BURROUGHS WELLCOME CO., Plaintiff, v. BARR LABORATORIES, INC., Defendant.	NO. 91-41-CIV-4-H
BURROUGHS WELLCOME CO., Plaintiff, v. NOVOPHARM, INC., Defendant.	NO. 92-134-CIV-4-H
BURROUGHS WELLCOME CO., Plaintiff, v. NOVOPHARM LTD., Defendant.	NO. 92-156-CIV-4-H

ORDER GRANTING JUDGMENT AS A MATTER
OF LAW IN FAVOR OF PLAINTIFF
BURROUGHS WELLCOME CO.
(Filed 7/22/93)

This matter is before the court on the plaintiff's motion for judgment as a matter of law filed June 30,

1993, and the plaintiff's renewed motion for judgment as a matter of law filed July 5, 1993. Also pending in this matter is the plaintiff's renewed motion for summary judgment filed June 18, 1993.

In the twenty-five months transpiring between the filing of the initial complaint in this consolidated patent infringement action on May 14, 1991, and the commencement of the trial on June 28, 1993, approximately five hundred forty-one pleadings have been filed and dozens of hearings on motions and discovery matters have been conducted by the court. The court has entered eighty-eight written orders and numerous bench rulings. Thus, the court is intimately familiar with the facts of this case and the legal contentions of the parties.

To state that the case has been hotly contested would be an understatement. The parties have amassed learned, experienced and sizable trial teams who have represented their clients zealously and competently.

The administrative complexity of conducting a trial of this magnitude has been enormous for the court and the parties. The sixty-year-old courtroom in New Bern, North Carolina, has been converted into a contemporary "high tech" facility utilizing "real time" court reporting and six computer-integrated video display monitors. It is highly conceivable that the cost of this trial for the parties exceeds $100,000 per day, in addition to the time and expense associated with this court and the jury. As this case enters its fourth week of trial, the parties estimate, somewhat conservatively the court suspects, that the trial will last an additional six to eight weeks.

With this preamble, the court will state briefly a synopsis of the procedural and factual background of the case. A more detailed statement of the procedural and factual background of the case can be found in the court's order dated June 3, 1993, denying plaintiff's motions for partial summary judgment.

PROCEDURAL BACKGROUND

Plaintiff Burroughs Wellcome Co. ("BW Co."), a research-oriented pharmaceutical company, owns and controls six United States patents covering various methods of using azidothymidine ("AZT") in the treatment of persons infected with the Human Immunodeficiency Virus ("HIV"). BW Co. manufactures and sells AZT under the brand name Retrovir. At issue in this case is the proper naming of inventors on the following six patents owned by BW Co.: 1) U.S. Patent No. 4,724,232, filed September 17, 1985, issued February 9, 1988; 2) U.S. Patent No. 4,828,838, filed October 21, 1987, issued May 9, 1989; 3) U.S. Patent No. 4,833,130, filed October 20, 1987, issued May 23, 1989; 4) U.S. Patent No. 4,837,208, filed October 20, 1987, issued June 6, 1989; 5) U.S. Patent No. 4,818,538, filed October 21, 1987, issued April 4, 1989; and 6) U.S. Patent No. 4,818,750, filed October 20, 1987, issued April 4, 1989. The court will refer to these patents collectively as "the BW Co. patents."

Defendants Barr and Novopharm Ltd. filed Abbreviated New Drug Applications ("ANDA") with the Food and Drug Administration ("FDA") on March 19, 1991, and June 26, 1992, respectively, seeking approval to manufacture and distribute a generic equivalent of Retrovir.

Both Barr and Novopharm Ltd. certified to the FDA, pursuant to 21 U.S.C. § 355 and 35 U.S.C. §§ 156, 271(e), that the BW Co. patents were either invalid or not infringed by the filing of their ANDAs. Barr asserted noninfringement for the reason, *inter alia*, that two scientists employed by the National Institutes of Health ("the NIH"). Dr. Samuel Broder and Dr. Hiroaka Mitsuya, were coinventors of the subject matter claimed in the six BW Co. patents but had not been named as inventors on the patents. Because Barr received a nonexclusive license from the NIH to exploit any patent rights the NIH, as the employer of Dr. Broder and Dr. Mitsuya, might have in the BW Co. patents, Barr alleged that its ANDA was not an act of infringement.

Similarly, Novopharm Ltd. asserted that Dr. Broder and Dr. Mitsuya were coinventors of the subject matter claimed in the BW Co. patents, but in support of its contention that the BW Co. patents were invalid. Novopharm Ltd. contended that BW Co. omitted Dr. Broder and Dr. Mitsuya from the BW Co. patents with the intent to deceive the patent office and thereby engaged in inequitable conduct before the patent office. Novopharm Ltd. asserted that this alleged inequitable conduct invalidated the BW Co. patents.

STATEMENT OF FACTS

The BW Co. patents name the following five scientists employed by BW Co. as inventors: Dr. Janet Rideout; Dr. David Barry; Dr. Sandra Lehrman; Ms. Martha St. Clair; and Dr. Phillip Furman (collectively referred to as "the BW Co. inventors"). BW Co. is a world leader in

antiviral therapy and experienced in retroviruses. BW Co. has been a leader in all aspects of the development of nucleoside analogs, particularly in their use as effective antiviral compounds.

The BW Co. inventors first began screening compounds for potential use as an AIDS therapy in 1984. In mid-1984, when the scientific community learned that AIDS was caused by a retrovirus, now referred to as HIV, the BW Co. inventors, specifically Ms. St. Clair, began screening compounds for antiretrovial activity against two murine retroviruses.[1]

On October 29, 1984, Dr. Rideout selected AZT, identified as BW Co. compound 509U81, for testing in the murine screens. Ms. St. Clair tested AZT in the murine screens and reported that AZT showed significant activity against FLV and HaSV at low concentrations. After obtaining these positive results, the BW Co. inventors met on December 5, 1984, to discuss patenting the use of AZT to treat patients infected with HIV. After subsequent meetings held in early January 1985, the BW Co. patent committee recommended that a patent application covering the use of AZT as an AIDS therapy be prepared for future filing.

On February 4, 1985, BW Co. sent a sample of AZT under the code name Compound S to Dr. Broder at the NIH for screening against HIV in human cells. In the letter accompanying the sample, Dr. Lehrman informed

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[1] The two murine retroviruses used by BW Co. for testing were the Friend leukemia virus ("FLV") and the Harvey sarcoma virus ("HaSV").

Dr. Broder that Compound S had been tested in murine and feline leukemia virus systems and that preliminary data was available showing that HIV replication had been inhibited at certain concentrations. Dr. Lehrman suggested that Dr. Broder screen Compound S at concentrations of 1, 5, 10, and 50 micromolars.

By February 6, 1985, a draft patent application for filing in the Untied Kingdom was prepared by BW Co. employees and its patent agents and attorneys. This draft application did not name the inventors, but it disclosed how to make various pharmaceutical formulations of AZT in an effective dosage range for the purpose of treating HIV infections in humans. The dosage ranges disclosed in the draft patent application encompassed the recommended dosage ranges approved by the FDA in 1987. Based upon the information contained in the draft patent application, three expert witnesses on behalf of BW Co.[2] and one expert witness designated by Barr[3] stated in depositions that the draft patent application teaches one of ordinary skill in the art how to use AZT to treat patients infected with HIV. The draft patent application was reduced to final form and filed in the United Kingdom on March 16, 1985.

Dr. Mitsuya tested Compound S against HIV in human cells in mid-February 1985. His tests demonstrated that Compound S was active against HIV. On February 20, 1985, Dr. Broder phoned Dr. Lehrman to report the results of Dr. Mitsuya's testing.

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[2] Dr. Katz, Dr. White, and Dr. Whitley.

[3] Dr. Levine.

DISCUSSION

Rule 50(a) of the Federal Rules of Civil Procedure provides that a court may grant judgment as a matter of law during a jury trial when, after a party has been fully heard on the issue, "there is no legally sufficient evidentiary basis for a reasonable jury" to find in favor of that party on that issue. In ruling on a Rule 50(a) motion, the court must consider all of the evidence in the light most favorable to the nonmoving party and determine "whether reasonable triers of fact could draw only one conclusion." *Bond v. Morton Buildings, Inc.*, 815 F. Supp. 944, 945 (S.D.W. Va. 1993). To avoid judgment as a matter of law, the nonmoving party must come forward with more than a scintilla of evidence to support the material aspects of his case. *Id.; see also Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 250-52 (1986).

Under Rule 56, summary judgment is proper where "the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law." The standard for summary judgment under Rule 56 is very similar to the standard for judgment as a matter of law under Rule 50(a).

Inventorship

The above facts are found by the court to be fully supported by the record. The parties and the court agree that the only real dispute in this case is the appropriate legal standard that will apply to these facts. The parties

candidly represent to the court that the resolution of the appropriate legal standard is outcome determinative.

In previous rulings, the court has defined conception as the formation in the mind of the inventor of a definite and permanent idea of the complete and operative invention as it is thereafter to be applied in practice. The court refused to adopt the legal standard asserted by the defendants in response to BW Co.'s motion for partial summary judgment that an inventor must have a "reasonable basis" for believing that an invention will work before conception can be complete.

The law of conception as understood by the court is comprised of two elements. The first element relates to the state of mind of the inventor – whether he had a definite and permanent idea of the complete and operative invention. This element is subjective; so long as the idea is sufficiently defined and preserved, the law does not require that the inventor's idea be reasonable, scientifically accurate, or capable of being proved. This legal definition of the first element of conception is the object of the parties' current dispute and permeates the whole of the defendants' case.

The second element asks whether the inventor's idea, as defined and preserved, enables one of ordinary skill in the art to reduce the invention to practice. This element is objective. The parties have no quarrel with the court's definition of the second element.

Defendant Barr has argued that the definition of conception requires that the BW Co. inventors must have a definite and permanent idea that AZT would be effective in treating humans suffering from AIDS. Barr contends

that it must be permitted to introduce evidence that challenges and undermines the murine screen used by the BW Co. inventors as a basis for their claimed definite and permanent idea that AZT would be effective in treating humans suffering from AIDS. Counsel for Barr has candidly stated that the heart of its case rests on the admissibility of evidence regarding the predictiveness, or lack thereof, of murine screens in forming the idea that AZT would be active against a human retrovirus.

In contrast, BW Co. contends that the phrase "definite and permanent" in the context of conception relates to the inventor's ability to describe and preserve his idea and *not* to the inventor's belief that the idea will actually work.

The court agrees with BW Co.'s contention regarding the definition of conception. The court does not believe that the phrase "definite and permanent idea" requires that the BW Co. inventors *know* that AZT would be effective in treating humans having AIDS. For conception to be complete, the law does not require an idea to be proven to actually work. The defendants candidly admitted that their case depends upon the evidence concerning the reliability or predictiveness of the murine screens used by the BW Co. inventors, which this court determines has no legal relevance.

In light of the candid representations of defendants' counsel that they would be unable to satisfy their burden of proof by clear and convincing evidence under the court's definition of the first element of conception, the court informed the defendants that it would consider BW Co.'s motions for judgment as a matter of law pursuant to

Fed. R. Civ. P. 50(a). With this notification, counsel for the defendants presented written offers of proof and were given additional time to further supplement their offers of proof. The court has very carefully reviewed the defendants' written offers of proof and supplemental offers of proof and afforded them an opportunity to be heard orally.

Having given the defendants the opportunity to be fully heard, the court will set forth its findings and conclusions in light of the legal definition of conception adopted by the court. Reviewing all of the evidence and resolving all inferences in favor of the defendants, the court finds no evidence which would enable the defendants to meet their burden of proof in this case. The pleadings in the case and the evidence presented in three weeks of trial testimony satisfy the court without doubt that no legally sufficient evidentiary basis exists for a reasonable jury to find that the BW Co. inventors did not have a complete conception of the invention independent of the testing performed by Dr. Broder and Dr. Mitsuya. The admissible evidence clearly establishes, and this court finds as a matter of law, that the BW Co. inventors formed a definite and permanent idea of using AZT as a therapy for AIDS without any inventive contribution from Dr. Broder and/or Dr. Mitsuya.

Furthermore, in light of all of the evidence, the court concludes that the BW Co. inventors' idea was sufficiently described to allow one of ordinary skill in the art to practice the invention. The evidence in the record shows that the draft patent application was sufficient to enable one of ordinary skill in the art to practice the invention, that is, to treat a patient infected with HIV

with an effective dosage amount of AZT. Thus, the evidence fully satisfies the second element of conception.

In reaching its legal conclusions on the elements of conception, the court has relied upon the holdings in such cases as *Hybritech, Inc. v. Monoclonal antibodies,* 802 F.2d 1367 (Fed. Cir. 1986), *Rey-Bellet v. Engelhart,* 493 F.2d 1380 (C.C.P.A. 1974), *MacMillan v. Moffett,* 432 F.2d 1270 (C.C.P.A. 1970), and *Applegate v. Scherer,* 332 F.2d 571 (C.C.P.A. 1964). The court notes further that a party who conducts tests wholly at the direction and instruction of another is merely a technician and not a conceiver and acts merely as a "pair of hands." The court finds that this last statement accurately characterizes the role played by Dr. Broder and Dr. Mitsuya. The evidence in the record shows that BW Co. sent Compound S to the NIH with specific instructions and directed the testing performed by Dr. Broder and Dr. Mitsuya.

Accordingly, the court concludes that BW Co. is entitled to judgment as a matter of law. The court finds that the evidence in this case is overwhelming and conclusive that the BW Co. inventors, and only the BW Co. inventors, first conceived of the idea of using AZT as a therapy for treating persons infected with HIV. Their definite and permanent idea was expressed in such documents as the February 6, 1985, draft patent application and the February 4, 1985, letter from Dr. Lehrman to Dr. Broder. In addition, the court has heard and considered the testimony of the inventors regarding their formation of the idea that AZT would be an effective AIDS therapy.

The court also finds that the evidence is equally strong in relation to U.S. Patent No. 4,818,750 claiming

the use of AZT to increase a patient's T-lymphocyte count. Novopharm Ltd. and Novopharm, Inc., contend that there is no evidence that the BW Co. inventors thought of this use until Dr. Broder and Dr. Yarchoan reported these results following the administration of AZT to a human during clinical trials. However, the court has heard substantial testimony that an increase in the T-lymphocyte count was an "obvious," natural phenomenon known to the BW Co. inventors that would result from the inhibition of a retrovirus.

Estoppel

Defendant Barr has also renewed its motion for partial summary judgment on the issue of estoppel, laches, and waiver. The court previously denied Barr's motion for partial summary judgment on these issues following oral argument on June 14, 1993. The court found that certain factual determinations precluded the entry of summary judgment.

Barr's primary contention in support of its motion is that the Property Clause of the United States Constitution holds that the government cannot be denied property rights through the assertion of the equitable doctrines of estoppel, laches, and waiver. Under the Property Clause and the cases applying it, government property may be disposed of only as authorized by Congress and government officials without proper authority cannot cause the government to lose its property rights. *See California v. United States*, 457 U.S. 273 (1982); *United States v. California*, 332 U.S. 19 (1947). Barr alleges that the government has never authorized the disposal of its patent rights

through estoppel, laches, or waiver, and, therefore, these equitable defense must be dismissed as a matter of law.

The court is not persuaded that the Property Clause is implicated in this action. Although a patent right is a property right, the rights being asserted by Barr in this case have not yet ripened into "property." The patent right being asserted[4] by Barr on behalf of the government in this action is the government's alleged ownership interest in the BW Co. patents.

Barr asserted in its previous motion for partial summary judgment on this issue that ownership rights in a patent inure *automatically* to the government. For the reasons stated below, the court disagrees with Barr's application and interpretation of this statement.

"At the heart of any ownership analysis lies the question of who first invented the subject matter at issue, *because the patent right initially vests in the inventor* who may then, barring any restrictions to the contrary, transfer that right to another, and so forth." *Beech Aircraft Corp. v. EDO Corp.*, 990 F.2d 1237, 1248 (Fed. Cir. 1993) (emphasis added). Only natural persons can be inventors.

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[4] The court questions whether the government is, in fact, asserting any rights or taking any action to protect its rights in this litigation. It is not a party to this proceeding, and it has repeatedly reminded the court that it is not a party to this proceeding. It participated very begrudgingly in discovery, which became the subject of numerous motions to compel culminating in an on-site inspection of the files of the NIH attended by this court. The only action taken by the government to preserve its alleged rights was the negotiation of a licensing agreement with the defendant Barr which obligated Barr to represent the government's interest in this action.

Id. at 1248 n.2. Because the government is not a natural person, the government cannot be an inventor. Therefore, patent rights cannot vest *automatically* in the government. The government must derive patent rights from an inventor.

In this case, the inventors from whom the government claims an ownership interest are Drs. Broder and Mitsuya. In order for the government to acquire an ownership interest in the BW Co. patents through Drs. Broder and Mitsuya, two conditions must be satisfied. First, Drs. Broder and Mitsuya must be inventors of the BW Co. patents. Second, Drs. Broder and Mitsuya must transfer, by assignment or otherwise, their ownership rights to the government.

Putting aside the first condition, the court finds that the government is not able to establish the second condition in order to support the contention that the government *has* an ownership interest to protect. Although a formal assignment is not necessary in order for the government to obtain ownership rights in the inventions of its employees, *see* Executive Order 10096; *In re Williams*, 228 U.S.P.Q. 381 (Comm'r Pat. 1985), federal regulations provide the proper procedures to be followed when a government employee seeks to establish patent rights. *See* 37 C.F.R. § 100.6(c)(3).

The record is devoid of any evidence showing that Dr. Broder and/or Dr. Mitsuya even filed or submitted an employee invention report identifying themselves as coinventors of the subject matter of the BW Co. patents. In fact, the court has found no evidence showing that Dr.

Broder and/or Dr. Mitsuya ever took *any* action to establish their status as coinventors. Therefore, the court finds no basis for finding that the government has a constitutionally-protected property interest in the BW Co. patents.

Accordingly, the court DENIES Barr's renewed motion for partial summary judgment on the issue of estoppel, laches, and waiver. Whether these equitable doctrines can be applied in this case is a question that cannot be decided as a matter of law. This ruling in no way expresses any opinion as to whether the elements of these doctrins [sic] can be satisfied in this case based upon the evidence.

CONCLUSION

For the foregoing reasons, the court hereby GRANTS BW Co.'s motion for judgment as a matter of law pursuant to Fed. R. Civ. P. 50(a)(1). The court finds that the BW Co. inventors had a complete conception, that is, they had a definite and permanent idea of a complete and operative invention as it was thereafter to be applied in practice, independent of any inventive contribution from Dr. Broder and Dr. Mitsuya. Having found that there is no basis in law for the contention that Dr. Broder and Dr. Mitsuya are coinventors, the court concludes that Novopharm, Inc., and Novopharm Ltd.'s defense of inequitable conduct fail as a matter of law and are hereby DISMISSED.

All other pending motions are hereby DISMISSED.

Pursuant to Fed. R. Civ. P. 50(a), judgment shall forthwith be entered in favor of the plaintiff Burroughs Wellcome Co.

This the 22nd day of July, 1993.

/s/ Malcolm J. Howard
MALCOLM J. HOWARD
United States District Judge

At New Bern, North Carolina
#19

United States Court of Appeals for the Federal Circuit

ORDER

Before MAYER, Circuit Judge, LOURIE, Circuit Judge, and SCHALL, Circuit Judge.

A petition for rehearing having been filed by the APPELLANT,

UPON CONSIDERATION THEREOF, it is

ORDERED that the petition for rehearing be, and the same hereby is, DENIED.

The mandate will issue December 22, 1994.

FOR THE COURT,
FRANCIS X. GINDHART, CLERK

Dated: December 15, 1994

by /s/ Diane M. Frye
Diane M. Frye
Chief Deputy Clerk

cc: DAN K. WEBB, ROBERT F. GREEN
E. ANTHONY FIGG

BURROUGHS WELLCOME
V. BARR LAB, 93-1503
(DCT – 91-41-CIV-4)

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Note: Pursuant to Fed. Cir. R. 47.6, this order is not citable as precedent. It is a public record.

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IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF NORTH CAROLINA
NEW BERN DIVISION
NO. 91-41-CIV-4-H
NO. 92-134-CIV-4-H
NO. 92-156-CIV-4-H

BURROUGHS WELLCOME CO.,

Plaintiff,

v.

BARR LABORATORIES, INC.,

Defendant.

BURROUGHS WELLCOME CO.,

Plaintiff,

v.

NOVOPHARM, INC.,

Defendant.

BURROUGHS WELLCOME CO.,

Plaintiff,

v.

NOVOPHARM LTD.,

Defendant.

SECOND MODIFIED JOINT OFFER OF PROOF ON INVENTORSHIP, DECEPTIVE INTENT AND INFRINGEMENT ISSUES

(Filed July 22, 1993)

I. INTRODUCTION

Novopharm Ltd. and Novopharm, Inc. (collectively "Novopharm") have alleged that U.S. Patent Nos. 4,724,232; 4,828,838; 4,833,130; 4,837,208; 4,818,538; and 4,818,750 are invalid because (a) Burroughs Wellcome Co. ("BW") failed to join as inventors scientists from the National Institutes of Health

* * *

toxicology studies, Dr. Elion testified that the inability of the pharmacology studies to give any evidence of the antiretroviral activity of AZT has been admitted by BW.

d. Activities of Duke/FDA/Sloan-Kettering

79. Beginning in the Fall of 1984, BW sent numerous compounds which had shown activity in its mouse test (including Compound S) to Dr. Kent Weinhold at Duke University, Dr. Rosen Hardy at Memorial Sloan-Kettering Cancer Center and Dr. Gerald Quinnan at the FDA for further testing.

e. Duke

80. Dr. Weinhold and BW agreed that BW would not send all compounds which BW had tested in this screen for testing by Duke because of the complexity of Duke's test, the limited capacity of Duke's test and the time-consuming nature of Duke's tests.

81. BW agreed to send to Duke only those compounds which had tested positive in the BW screen, except for some negative controls. As such, the BW screen

was a screen to eliminate those compounds that did not test positive.

82. Duke initially performed two assays on compounds it received from BW for testing. One test was a direct reverse transcriptase assay fro measuring the activity of a compound against reverse transcriptase in a cell-free environment. The second test was a chronic infection assay for testing a compound for activity against HIV in chronically infected human cells.

83. On or about December 4, 1984, BW sent Compound S (AZT) to Dr. Weinhold for screening. On December 10, 1994 Dr. Weinhold reported to Dr. Lehrman that Compound S showed no activity in the direct RT assay. (TX4609; Weinhold Tr. 44, 48-49, 134-135; TX-2022; TX-4429).

84. On December 10, 1984, Dr. Weinhold reported to Dr. Lehrman the results of the chronic infection assay. (TX-2022; TX-4429) The results of the chronic infection assay showed a reduction in both reverse transcriptase activity and in cell viability. Those results meant that Compound S was *toxic* in the assay and that the assay did not show an antiviral effect on AZT. (Weinhold Tr. 143, 148).

85. As late as February 1, 1985, St. Clair reported that Compound S had shown no activity in the Duke chronically-infected cell assay. (TX-2021)

86. At some time, Dr. Weinhold began the development of a third test for determining the activity of a compound against HIV. In the third test, human cells newly infected with HIV were used. (Weinhold Tr. 150)

87. Activity of a compound in the newly-infected cell assay was determined by measuring reverse transcriptase activity. (Lehrman Vol. 1, Tr. 138-140).

88. Dr. Weinhold's early attempts at testing the activity of AZT in newly-infected cells were unsuccessful. Dr. Lehrman's notes of a December 28, 1984 telephone report from Dr. Weinhold reveal that Dr. Weinhold's newly-infected cell assay still needed work. (TX-2034; Lehrman Vol. 1, Tr. 129-130).

89. While Dr. Weinhold may have begun to experiment with his newly-infected cell assay in January to mid-February, 1985, (Weinhold Tr. 151; Lehrman Vol. 1, Tr. 140), it was not until March 19, 1985 that Dr. Weinhold first provided BW data showing the activity of Compound S against HIV in newly-infected cells. (TX-2035; Lehrman Vol. 1, Tr. 140). The timing Dr. Weinhold's positive results relative to Dr. Broder is consistent with Dr. Bolognesi's recollection that "it was always our impression that . . . Dr. Broder's laboratory was the first to achieve a positive result with Compound S". (Bolognesi Tr. 36).

90. The researchers at Duke understood that Dr. Broder's laboratory was the first to achieve a positive result with Compound S.

91. BW did not receive results indicating an antiviral effect for AZT from Dr. Weinhold's screen with the live AIDS virus and employing newly infected cells until after BW had received from Dr. Broder results indicating an anti-HTLV-III effect for Compound S.

92. Proffers 79-90 find support in, *inter alia*, the deposition testimony of Dr. Weinhold, Dr. Bolognesi, Dr. Furman, Dr. Lehrman, and Ms. St. Clair, and TX-4025, TX-4026, and TX-4027.

f. FDA

93. In late November, 1984, BW sent a number of compounds, including Compound S, to Dr. Quinnan, Division Director, Division of Virology in the Center for Biologies Evaluation and Research at the Food and Drug Administration (FDA) to run in Dr. Quinnan's assay.

94. Dr. Quinnan requested the compounds from BW and BW agreed to provide the compounds for the purpose of Dr. Quinnan's testing.

95. Dr. Quinnan tested the compounds for activity against the AIDS virus to determine whether the compounds had activity.

96. Dr. Quinnan conducted the tests on behalf of public health, not on behalf of BW.

97. Dr. Quinnan tested compounds on cultures of H9 (human) cells chronically infected with virus. Dr. Quinnan also tested compounds on cultures of H9 cells newly infected with virus.

98. From time to time during December 1984, January 1985 and February 1985, Dr. Quinnan reported to Dr. Lehrman of BW on the progress of his tests. (TX-4301; TX-2040; TX4309; TX4310; TX-2042; Quinnan Tr. 221)

99. BW did not receive results indicating an antiviral effect for AZT from Dr. Quinnan's screen with the

live AIDS virus employing newly infected cells until after BW had received from Dr. Broder results indicating an anti-HTLV-III effect for Compound S.

100. Dr. Lehrman's notes of telephone conversations with Dr. Quinnan reflect that at no time prior to February 20, 1985 when Dr. Broder reported the positive results he and Dr. Mitsuya had achieved with AZT, did Dr. Quinnan report to BW that Compound S was active against HIV in Dr. Quinnan's assays. (TX-4308; TX-2040; TX-4309; TX-4310; TX-2042; Quinnan Tr. 224-225, 229-234, 235-236, 238-239; Lehrman Vol. 2, Tr. 17).

101. Although Dr. Quinnan testified that he had obtained results "which indicated that the compounds probably inhibited replications of HIV" and that he had reported such results to BW, Dr. Quinnan further testified that his results were equivocal and that he did not have enough data to know whether the reduced viral replication he had observed was due to "toxic effects" or whether the compound was acting as a "true antiviral". (Quinnan Tr. 247 - 253)

102. Thus, Dr. Quinnan's assay was not able to distinguish activity of a compound tested from possible toxic effects of the compound.

103. The results obtained in Dr. Quinnan's assay for AZT, prior to March 1, 1985 did not distinguish between an anti-HIV effect and cytotoxity. (Quinnan Tr. 255-256)

104. Dr. Quinnan had described his methodology to BW sufficiently that BW was aware that his assay would not differentiate between a toxic effect and an antiviral effect.

105. Dr. Quinnan further testified that the information he had available based on the results of his tests, even knowing that the compound he was testing was AZT would not have allowed for a determination to be made whether or not it was to be effective against AIDS. (Quinnan Tr. 250-252; 259-262)

106. Even after Dr. Broder had reported his positive results to BW, Dr. Quinnan was "still vague" about the activities of Compound S and advised BW that repeat assays were in progress. (TX-2044; Lehrman Vol. 2, Tr. 35-39)

107. Even BW did not rely on Dr. Quinnan's test results. The people at BW who were interested in AZT, including possibly Dr. Lehrman, Dr. Barry and Dr. Furman, did not have confidence in Dr. Quinnan's results. It was a pervasive feeling at BW that Dr. Quinnan's result [sic] were not trustworthy or reliable. (Wise Tr. 97-99).

108. Proffers 92-106 find support in, *inter alia*, the deposition testimony of Dr. Quinnan, Dr. Wise, Dr. Lehrman, Dr. Furman, Ms. St. Clair, TX-4030, TX-4031, TX-4034, TX-4035, TX-4423, TX-4424, and TX-4425.

g. Sloan-Kettering

109. Dr. Hardy at Sloan-Kettering tested compounds submitted to him by BW for anti-retroviral activity in a screen using feline (cat) leukemia virus in cat cells. The feline leukemia virus differs from HIV. Hardy's test used cat cells chronically-infected with the feline leukemia virus. Hardy's test was not predictive of the activity of a compound against HIV.

110. A goal of the testing in cats was to find a treatment for feline leukemia virus in cats, as testified by Dr. Barry. (TX-4036, Deposition Testimony of Drs. Hardy, Furman, Ruprecht, Furmanski and Temin)

h. Toxicology/Pharmacology

111. Between 1981 and 1984, BW and its parent company, the Wellcome Foundation, extensively investigated AZT as an antibacterial drug and found no human use for AZT as a result of that investigation. BW, in 1984, did not consider that AZT would be a practical antibacterial agent for human use. Prior to November, 1984, AZT had no established use in humans.

112. BW investigated AZT as a veterinary drug.

* * *

144. Proffers 127-142 find support in, *inter alia*, the deposition testimony and expected trial testimony of Dr. Broder, Dr. Lehrman, and Dr. Bolognesi.

j. Drs. Broder and Mitsuya Discover Activity of AZT In Human Cells

145. On February 4, 1985, Lehrman sent Compound S to Dr. Broder and indicated that Compound S had demonstrated activity against mouse retroviruses.

146. At the time BW transmitted a sample of AZT for testing to Dr. Broder, BW's Lehrman told Dr. Broder that if Dr. Broder's results were encouraging, BW could expedite its progress into clinical trials. (TX-4401) The February 4 letter demonstrates that whatever preliminary

results might already have been obtained had not convinced BW that AZT was likely to be a treatment for AIDS. Lehrman keyed the future development of AZT to Broder and Mitsuya's results: "Hopefully, if you have encouraging results in a month or so we can expedite its progress into the clinic." (TX-416)

147. BW was waiting for the test results before it would or could begin clinical trials from Dr. Broder because BW did not know if Compound S would be active against HIV. Contrary to what the BW scientists now claim, if St. Clair's tests, along with those of Duke and the FDA were predictive and positive, BW would not have needed the results from Dr. Broder before it would start clinical trials.

148. Dr. Mitsuya tested Compound S with the ATH8 cell line in mid-February of 1985, and on February 20, 1985, Dr. Broder reported to Lehrman that Compound S was active against HIV in human cells, i.e., *in vitro*. (TX-4045)

149. Drs. Broder and Mitsuya discovered for the first time that AZT was active against HIV.

150. In February of 1985, the testing performed by Dr. Mitsuya required more than routine skill.

151. In February of 1985, the work performed by Dr. Mitsuya was not routine screening, but rather was original research requiring interpretation and intellectual contribution to obtain and analyze the results.

152. In 1984-1985, BW and the NIH were engaged in a collaboration based upon intellectual exchange for the purpose of developing a therapy for AIDS.

153. Dr. Broder confirmed by letter the telephone call in which he reported for the first time that Compound S was active against HIV in human cells. (TX-2053A)

154. Only after Dr. Broder advised BW of the positive test results for AZT did BW take action to move AZT forward as a treatment for AIDS. (TX-4044)

155. Marty St. Clair admitted that only after Dr. Broder reported the results of the activity of AZT against HIV did things start to happen and so fast that she kind of almost got lost behind. (TX-2009)

156. Within days after Dr. Broder's report of the discovery of activity of AZT against HIV, BW invited Dr. Broder to visit BW in North Carolina, and that visit occurred only a few days later, on March 1. (TX-4044, TX-4046)

157. On March 18, 1993, only a few weeks after receiving the positive results from Dr. Broder (TX-2055), Lehrman and Furman wrote the official proposal to establish a Project Group for AZT at BW. (TX-2294)

158. At the March 1, 1985 conference, BW scientists and Dr. Broder reviewed the NCI data concerning AZT and, with Dr. Broder's assistance, based upon his prior experience with suramin, started to plan clinical trails for AZT. (TX-4046)

159. Dr. Bolognesi, Dr. Weinhold and Dr. Quinnan did not attend the March 1 meeting and no meeting with them occurred to discuss their data for Compound S. (TX-4046)

160. Broder and BW continued to collaborate after Broder and Mitsuya determined the effect of AZT against the live AIDS virus. Broder and Mitsuya continued to test AZT in a battery of tests which were not directed by BW but the data for which was shared with BW. Broder collaborated with BW to develop the protocol for testing AZT in the clinic. Broder in fact supervised the first use of AZT. (Broder and Mitsuya Trial Testimony.)

161. BW itself considered Broder's contribution important and inventive. BW acknowledged on numerous occasions the central role played by Broder after his work had been completed and before this lawsuit was filed. BW stated in its internal newsletter, "Wellcome News," published in October 1985:

> In early 1985, *NCI* called Burroughs Wellcome with its findings: (AZT] was active against the human AIDS virus. In fact, *researchers at the NCI* said, it was the most active compound they'd looked at so far. The green light was on.

162. The BW internal publication, "The Retrovir Story by B.W. Co. People," stated:

> In February [1985], *Sam Broder* called Sandi Lehrman to report that [AZT] was positive against HIV. We knew we really had something then. Things really began to move incredibly fast.

163. Similarly at a press conference held on March 23, 1987, David Barry stated:

> In close collaboration with us, testing at the National Cancer Institute by Dr. Samuel Broder and his colleagues in late 1984 and early 1985

> showed that Retrovir did inhibit the multiplication of the human AIDS virus in the test tube.

164. A "chronological listing of the key activities" in AZT's development compiled by BW in 1985 indicates that within two weeks after receiving Dr. Broder's test results the decision was reached to move ahead and develop AZT as an antiviral.

165. The development of AZT at BW depended on the results of Dr. Broder's experiments with human cells infected with HIV.

166. During an interview conducted before this lawsuit, Dannie King, BW's AZT project leader, sated that BW reached the decision to move forward with AZT only after Drs. Broder and Mitsuya's work:

> [a]t the time the activity was identified – confirmed, let's say – against the AIDS virus, and that was in early 1985 that was confirmed by [Broder] – then the decision was taken by Cuatrecasas [to go forward with AZT].

(TX 2207 at 180564-65).

167. Sandi Lerhman of BW confirmed that AZT's development hinged upon the results of Broder's experiments with human cells infected with HIV: "With the demonstration by Dr. Broder that [AZT] is a potent inhibitor of HTLV-3 *in vitro*, plans for clinical evaluation of this drug are in progress." (TX 2295).

168. Proffers 144-166 find support in, *inter alia*, the deposition testimony and expert testimony of Dr. Broder, Dr. Mitsuya and Dr. Yarchoan, and the laboratory notebooks of Dr. Mitsuya.

k. Patent Activities

169. The Wellcome Foundation Patent Department routinely filed the first patent applications on BW's potential inventions and those applications routinely were filed first in the United Kingdom.

170. Mr. Garrett of the Wellcome Foundation Patent Department met appropriate BW personnel and with the BW patent committee to obtain information to draft the patent application for AZT.

171. Michael Jackson, the head of the Patent Department of The Wellcome Foundation, was responsible for deciding whether or not to file patent applications and when, not the BW patent committee. Nevertheless, before the NIH discovered the activity of AZT against HIV, the decision to file a patent application on

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